A DOCPHOENIX

Office Action Summary	Application No.	Applicant(s)	
	09/743,205	DURING, KLAUS	
	Examiner	Art Unit	
	Juliet C Einsmann	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,14 and 16-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13,14,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is written in response to applicant's correspondence submitted 9/27/02, paper number 13. Claims 1, 6, 7, 8, 9, and 10 have been amended. Claims 12 and 15 have been cancelled. Claims 18-20 are withdrawn from prosecution. Claims 1-11, 13, 14, and 16-20 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

2. Applicant's election of Group I in Paper No. 11 and 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

3. The substitute specification filed 27 September 2002 has been entered. However, the specification is objected to as containing new matter.

4. The substitute specification filed 27 September 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Paragraph [0028] of the substitute specification is provides an incorporation by reference that significantly expands the scope of the disclosure and is therefore new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-10, 12, 14, 15, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 16 are indefinite over the recitation of "a protein processing precursor fibrous protein" because it is confusing what is intended by this language. Amendment of the claims to read a protein which processes a precursor fibrous protein would overcome this rejection. This rejection is reiterated from the previous office action because no amendment was set forth to address it, nor were arguments set forth addressing the rejection of claims 14 and 16.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1, 2, 3, 4, 6, 8, 10, 11, 12, 14, 15, and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kivirikki *et al.* (WO 97/38710).

Kivirikki *et al.* teach a process for the production of a fibrous protein comprising (a) expressing a precursor fibrous protein in a plant cell (p. 10, lines 5-9); and (b) incubating the precursor fibrous protein with a protein processing it (p. 8, lines 13-16; p. 9, lines 18-20). Kivirikki *et al.* teach that the processing protein can be lysine oxidase (p. 19, lines 14-26), and further teach methods in which lysine oxidase is expressed in the same host cell as the precursor protein (p. 8, lines 13-16) or in a different host cell (examples 1 and 7). Kivirikki *et al.* teach the expression of precursor protein that is procollagen, thus the fibrous protein produced is a collagen. Kivirikki *et al.* thus provide plant cells expressing a precursor fibrous protein as well as plant cells expressing a protein which processes a precursor fibrous protein. Further, Kivirikki *et al.* provide cells which are available on a multiplication media, since all of the cells taught by Kivirikki *et al.* are in grown in cultures.

9. Claims 1, 5, 7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Daniell *et al.* (US 6004782).

Daniell *et al.* teach methods for the production of a fibrous protein comprising expressing a precursor fibrous protein in a plant cell ; and incubating the precursor fibrous protein with a protein processing it (Col. 15, lines 55-65). Daniell *et al.* teach methods wherein the cell is part of a plant. The precursor molecules taught by Daniell *et al.* include $(GVGVP)_{120}$ and G-$(VPGVG)_{19}$-VPGV which are tropoelastins or a derivative and a fragment thereof (Col. 19,

Example 4 and Col. 20, Example 20), and the fibrous protein being produced is therefore an elastin.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kivirikki *et al.* (WO 97/38710) in view of Zhang *et al.* (Plant Cell Reports (1996) 16:174-179).

Kivirikki *et al.* teach a process for the production of a fibrous protein comprising (a) expressing a precursor fibrous protein in a plant cell (p. 10, lines 5-9); and (b) incubating the precursor fibrous protein with a protein processing it (p. 8, lines 13-16; p. 9, lines 18-20). Kivirikki *et al.* teach that the processing protein can be lysine oxidase (p. 19, lines 14-26), and further teach methods in which lysine oxidase is expressed in the same host cell as the precursor protein (p. 8, lines 13-16) or in a different host cell (examples 1 and 7). Kivirikki *et al.* teach the expression of precursor protein that is procollagen, thus the fibrous protein produced is a collagen. Kivirikki *et al.* thus provide plant cells expressing a precursor fibrous protein as well as plant cells expressing a protein which processes a precursor fibrous protein. Further, Kivirikki *et al.* provide cells which are available on a multiplication media, since all of the cells taught by Kivirikki *et al.* are in grown in cultures.

Kivirikki *et al.* do not teach methods in which the cells are available in a transgenic plant, nor do they teach methods in which the precursor protein is a tropoelastin.

Zhang *et al.* teach methods for the production of production of a fibrous protein which comprise (a) expressing a precursor fibrous protein in a plant cell, wherein the plant cell is available as part of a plant and therefore as part of a multiplication material since the cells of the plants are constantly dividing (p. 175). Zhang *et al.* are producing tropoelastin polymers or fragments or derivatives thereof (p. 175-175).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the methods taught by Kivirikki *et al.* with those taught by Zhang *et al.* to have arrived at methods for producing transgenic plants that express fibrous precursor proteins. The ordinary practitioner would have been motivated by Zhang *et al.*'s teaching that it is advantageous to produce such proteins in plants because it is expensive to produce precursor proteins by routine fermentation methods, and a strategy for reducing production cost "would be to produce polymers in plants, because plants are cheap to grow on a large scale." Furthermore, It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have incubated the tropoelastins produced in the methods taught by Zhang *et al.* with the processing proteins taught by Kivirikki *et al.* in order to achieve the goal of producing cross-linked polymers for the commercial utilities taught by Zhang *et al.* (p. 174). Thus, given the combined teachings of Kivirikki *et al.* in view of Zhang *et al.* the instantly claimed invention is *prima facie* obvious in view of the prior art.

Response to Remarks

The rejections under 112 2nd paragraph were overcome by applicant's amendments, with the exception of the rejection of claims 14 and 16 reiterated above. This rejection is reiterated because applicant did not amend claim 14 nor did applicant provide arguments addressing the rejection.

Applicant argues that the presently claimed invention is not anticipated by Kivirikki et al. because Kivirikki et al. do not provide disclosure that would enable the production of a fibrous protein in plant cells. However, Applicant does not provide any reasoning to support this conclusion. It appears that applicant is suggesting that because Kivirikki et al. do not exemplify the production of collagen in plant cells in particular that their disclosure is not enabling. It is noted that the instant specification does not exemplify the claimed invention either, but in view of the teachings of the prior art, no enablement rejection was set forth. Applicant states that the mere mention that one could theoretically make procollagen or collagen in plant cells is not sufficient to meet the threshold of enabling disclosure in accordance with the law. However, this is not an accurate representation of the disclosure of Kivirikki et al. Kivirikki et al. provide examples of vectors and promoters for use in expressing nucleic acids that will produce the fibrous protein in plant cells (p. 20-21), as well as direction for the infection, transformation and transfection of host cells (p. 29). Finally, Kivirikki et al. provide an example wherein procollagen is produced and correctly folds in a trasfected cell. Thus, while Kivirikki et al. do not specifically exemplify the production of fibrous proteins in plant cells, they certainly provide the teaching of such cells and adequate disclosure to enable their disclosure. MPEP 2123 teaches

that "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments."

Applicant argues that the presently claimed invention is not anticipated by Daniell et al. because Daniell et al. do not provide disclosure that would enable the production of a fibrous protein in plant cells. As in the arguments concerning Kivirikki et al., applicant does not provide any reasoning to support this conclusion. It appears that applicant is suggesting that because Kivirikki et al. do not exemplify the production of collagen in plant cells in particular that their disclosure is not enabling. It is noted that the instant specification does not exemplify the claimed invention either, but in view of the teachings of the prior art, no enablement rejection was set forth. Applicant states that the mere mention that one could express a fibrous protein in plant cells is not a sufficient basis for a rejection under section 102. However, this is not an accurate representation of the disclosure of Daniell et al. Daniell et al. provide examples of vectors and promoters for use in expressing nucleic acids that will produce the fibrous protein in plant cells (Col. 13, lines 35- Col. 14), as well as direction for the infection, transformation and transfection of host cells (Col. 12, lines 32-56). Daniell et al. specifically discuss the production of fibrous proteins in plant cells in Examples 4, 5, 6 and 7. Finally, Daniell et al. provide an example wherein procollagen is produced and correctly folds in a trasfected cell (Example 1). Thus, while Daniell et al. do not specifically exemplify the production of fibrous proteins in plant cells, they certainly provide the teaching of such cells and adequate disclosure to enable their disclosure.

Applicants argue that the combination of Kivirikki and Zhang does not suggest the presently claimed invention because Kivirikki cannot be properly applied in an obviousness

rejection because it is not enabling for the methods claimed herein. The reasons relied upon in this argument are those that have been addressed previously. Furthermore, the fact that the teachings of Kivirikki et al. were enabled at the time the invention was made is underscored by the disclosure of Zhang et al. who specifically exemplify the production of protein tropoelastin polymers in plants. Applicant argues that Zhang does not fill this deficiency because Zhang does not provide the step of processing the precursor fibrous protein with a processing protein so that a fibrous protein is produced, and because Zhang is limited to expressing tropoelastin polymers, and does not extend to expressing procollagen, collagen, or elastin. However, this is not persuasive. This portion of the argument is not persuasive because it is a piecemeal analysis which disregards the teachings of Kivirikki et al. who specifically provides for these limitations, as is addressed in the rejection reiterated herein. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Thus, the rejections are maintained.

Conclusion

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

Juliet C Einsmann
Examiner
Art Unit 1634

December 23, 2002